

METHOD AND APPARATUS FOR GENERATING A TWELVE-LEAD ECG
FROM FEWER THAN TEN ELECTRODES

RELATED APPLICATIONS

[0001] This application is a continuation of United States Patent Application No. 09/752,140, filed December 29, 2000.

BACKGROUND OF THE INVENTION

[0002] The invention relates to a method and apparatus for generating a twelve-lead electrocardiogram (ECG) from a plurality of fewer than ten electrodes for attachment to a patient in the standard ten-electrode, twelve-lead ECG positions.

[0003] A standard, resting ECG is acquired with ten electrodes. Four of the ten electrodes are placed on the patient's limbs. Six of the ten electrodes are attached to the patient's chest over the heart. The signals acquired by the ten electrodes are amplified and processed to generate twelve channels of ECG data. The twelve channels or leads are generally split into two groups – the frontal plane leads (I, II, III, aVR, aVL, aVF) and the horizontal plane leads (V1, V2, V3, V4, V5, V6).

[0004] A standard, resting ECG has several limitations. First, the six electrodes attached to the patient's chest inhibit the clinicians' access to the patient's chest. Second, clinicians may not be able to attach all six chest electrodes due to wounds or bandages on the patient's chest. The electrodes, leadwires, and amplifiers necessary to acquire twelve channels of ECG data increase the cost of the ECG machine. Fourth, the amount of data representing twelve channels of ECG generally exceeds the maximum amount or bandwidth that typical telemetry units are able to transmit.

[0005] U.S. Patent No. 4,850,370 provides a solution to some of the above-described limitations. The '370 Patent discloses a method of sensing and analyzing the electrical activity of the human heart by sensing the voltage signals generated by the heart between four electrodes located at key positions on the surface of the subject's body. A signal processing means produces electrocardiographic signals corresponding to the lead signals of a twelve-lead electrocardiogram.

[0006] FIG. 3 illustrates the electrode placement for the method of generating a twelve-lead ECG from four electrodes as disclosed in the '370 Patent. The four electrodes are designated as E, A, S, and I (hereinafter referred to collectively as the "EASI electrodes"). The E electrode is located at the front midline over the lower end of the sternum. The A electrode is located at the left mid-axillary line. The S electrode is located at the front midline over the upper end of the sternum. The I electrode is located at the right mid-axillary line.

[0007] The EASI electrodes are coupled to a signal processor (not shown) having a first stage and a second stage. The first stage of the signal processor does not generate the twelve-lead ECG, but rather generates xyz vectorcardiographic signals. The twelve-lead ECG is then derived from the xyz vectorcardiographic signals in the second stage of the signal processor. As a result of the two stage signal processing, each of the twelve leads generated from the EASI electrodes are mathematically generated. In other words, none of the leads are the same as the leads that would be generated from the electrical signals of a standard ten-electrode, twelve-lead ECG.

[0008] The method of the '370 Patent has several limitations. First, the four electrodes are placed in non-standard positions, i.e. positions different from the electrode positions for a standard ten-electrode, twelve-lead ECG. This requires clinicians to be trained specifically for the method of the '370 Patent. Second, twelve leads of ECG data are generated, but all twelve leads are generated mathematically. None of the twelve leads in the method of the '370 Patent are the same as the leads that would be generated from a standard ten-electrode, twelve-lead ECG. Rather, all twelve leads are mere approximations of the leads of a standard ten-electrode, twelve-lead ECG. Third, two of the four electrodes are placed directly over the sternum. The sternum is cracked for all open chest surgeries in a procedure called sternotomy. Thus, the clinician may not be able to attach the two electrodes directly over the sternum due to sternotomy wounds and bandages.

SUMMARY OF THE INVENTION

[0009] In light of the limitations described above, a need exists for a method and apparatus for generating a twelve-lead ECG from less than ten electrodes for attachment to a patient in the standard ten-electrode, twelve-lead ECG positions.

[0010] Accordingly, the invention provides a method and apparatus for generating a twelve-lead ECG from fewer than ten electrodes for attachment to a patient in at least some of the standard ten-electrode, twelve-lead ECG positions.

[0011] The apparatus is a device for acquiring and processing electrical signals produced by a patient's heart. The device includes fewer than ten electrodes for attachment to the patient. Each electrode is attached in a respective one of the standard ten-electrode, twelve-lead ECG positions. The device includes a signal processor connected to the electrodes. The signal processor acquires electrical signals from the electrodes and generates a twelve-lead ECG from the electrical signals. The signal processor generates less than twelve of the leads mathematically.

[0012] For the method of the invention, a plurality of less than ten electrodes are attached to the patient. Each electrode is attached in a respective one of the standard ten-electrode, twelve-lead ECG positions. Electrical signals are acquired from the electrodes and a twelve-lead ECG is generated from the acquired electrical signals. But not all twelve leads are generated mathematically.

[0013] The device employs multiple-linear regression using expansion-coefficient equations to mathematically generate fewer than twelve of the leads. The expansion-coefficient equations are determined either from ECGs from a hospital's general population, from a sub-population of the hospital's general population, or from ECGs previously acquired from the patient. The invention employs multiple-linear regression to generate the leads that are missing due to the use of fewer than ten electrodes. Stated differently, some of the leads (for the twelve lead ECG) are generated from a standard electrical manipulation of the signals acquired from the

electrodes, while the remaining leads are generated mathematically by a signal processor.

[0014] The invention further includes a telemetry unit to acquire electrical signals from the plurality of less than ten electrodes and to transmit the electrical signals to the signal processor to generate a twelve-lead ECG.

[0015] It is an advantage of the invention to reduce the number of electrodes, leadwires, and amplifiers necessary to acquire a twelve-lead ECG while still employing some of the standard electrode positions commonly known to clinicians.

[0016] It is another advantage of the invention to provide a method of generating a twelve-lead ECG without generating all twelve leads mathematically.

[0017] It is still another advantage of the invention to provide a method of electrode placement that allows for better access by clinicians to the patient's chest.

[0018] It is still another advantage of the invention to provide a method of electrode attachment that avoids electrode placement over the sternum in order to avoid sternotomy wounds and bandages.

[0019] It is still another advantage of the invention to reduce the bandwidth required to transmit the acquired electrical signals representing the patient's ECG from a telemetry unit to a signal processor.

[0020] It is still another advantage of the invention to provide a telemetry system capable of monitoring the ECG of more than one patient.

[0021] Various other features and advantage of the invention are set forth in the following drawings, detailed description and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] FIG. 1 illustrates the apparatus embodying the invention.

[0023] FIG. 2 illustrates the electrode placement for a standard or resting ten-electrode, twelve-lead ECG.

[0024] FIG. 3 illustrates the electrode placement for the method of the '370 Patent.

[0025] FIG. 4 illustrates the electrode placement for the most preferred embodiment of the invention.

[0026] FIG. 5 illustrates the electrode placement for a less preferred embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0027] Before one embodiment of the invention is explained in full detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the following drawings. The invention is capable of other embodiments and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of "including" and "comprising" and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items.

[0028] FIG. 2 illustrates the electrode placement for a standard or resting ten-electrode, twelve-lead ECG (hereinafter "standard ECG"). For a standard ECG, ten electrodes are attached to a patient's body. One electrode is attached to each of the patient's four limbs at the wrists and ankles. These electrodes are referred to as left arm (LA), right arm (RA), left leg (LL), and right leg (RL). The RL electrode generally serves as an electrical ground. In practice, the limb electrodes are attached at any point along the limb from the wrist or ankle towards the point of attachment of the limb to the trunk of the body. As shown in Figure 2, six electrodes are attached in standard positions on the chest around the heart. As is commonly known in the art, the ten electrodes are connected via leadwires and resistor networks to enough amplifiers to record twelve separate ECG channels or leads.

[0029] The twelve leads are split into two groups: the frontal plane and the horizontal plane. If a straight line were drawn from the heart to each wrist and each ankle, the four lines would lie in the frontal plane. Similarly, if a straight line were drawn from the heart to each of the six electrodes placed on the patient's chest, the six lines would generally lie in the horizontal plane. The leads in the frontal plane are referred to as the frontal leads, the limb leads, or the Einthoven leads, and include leads I, II, III, aVR, aVL, and aVF. The leads in the horizontal plane are referred to as the horizontal leads, the precordial leads, the chest leads, or the unipolar leads, and include leads V1, V2, V3, V4, V5, and V6.

[0030] The frontal leads are obtained with various permutations of the LA, RA, and LL electrodes, with the RL electrode serving as an electrical ground. The frontal leads are comprised of the potential between two of the limb electrodes: lead I corresponds to the potential between LA and RA, lead II corresponds to the potential between LL and RA, and lead III corresponds to the potential between LL and LA.

[0031] Leads aVR, aVL, and aVF, referred to as the augmented leads, are comprised of the potential between one electrode and a reference input, the reference input being the average of two electrodes. For example, lead aVF is the signal between LL and a reference input, where the reference input is the average of the potentials at electrodes RA and LA.

[0032] The horizontal leads are obtained with various permutations of the six electrodes attached to the patient's chest, in addition to three of the four limb electrodes. Each of the six horizontal leads is comprised of the signal between the potential at the particular electrode placed on the patient's chest and the potential at Wilson's central terminal. Wilson's central terminal refers to the average potential between the RA, LA, and LL electrodes. For example, lead V1 is the signal between electrode V1 and Wilson's central terminal.

[0033] Cardiologists are trained to recognize the subtle characteristics of ECG waveforms and to correlate the subtle characteristics to specific cardiovascular events and conditions. In general, any ECG machine that does not generate the standard

twelve-lead ECG is undesirable, because cardiologists depend on consistency for their interpretation of ECG waveforms. Accordingly, the preferred embodiments of the present invention provide a method and apparatus for generating a standard twelve-lead ECG from fewer than the ten electrodes.

[0034] The method and apparatus of the present invention generates a plurality of leads that are the same as the leads that would be generated from the electrical signals of a standard ECG. Before the preferred embodiments of the invention are described, it should be understood that the essence of the invention includes the use of any number of electrodes and any configuration of electrode placement, as long as fewer than ten electrodes are each attached to the patient in a respective one of the standard ECG positions, and a twelve-lead ECG is derived therefrom.

[0035] The most preferred electrode placement is illustrated in FIG. 4. Specifically, FIG. 4 illustrates the electrode placement for six electrodes used to acquire electrical signals from the patient's heart. Preferably, only two electrodes are attached to the patient's chest. V1 is attached to the patient in approximately the fourth intercostal space at the right border of the patient's sternum. V5 is attached to the patient in approximately the fifth intercostal space at the patient's anterior axillary line. Four electrodes are attached to the patient's limbs. The electrodes attached to the right arm, left arm, and left leg acquire electrical signals, while the electrode attached to the right leg generally acts as an electrical ground.

[0036] In the most preferred embodiment, electrodes V2, V3, V4, and V6 are not attached to the patient. Thus, leads V2, V3, V4, and V6 corresponding to the omitted electrodes must be derived mathematically. However, unlike the known prior art, only these four leads need to be derived mathematically. Eight of the leads, namely leads I, II, III, aVR, aVL, aVF, V1, and V5, are generated in the same manner as in a standard ten-electrode, twelve-lead ECG.

[0037] Electrodes V1 and V5 are the most preferred chest electrodes for a number of reasons. First, the information in the V1 lead is very important to clinicians. Lead V1 is, of course, most accurate if an electrode is placed directly in the V1 position.

Second, the positions of the V1 and V5 electrodes do not interfere with the clinician's access to the patient's chest as much as the positions of the V2, V3, and V4 electrodes. Even with the V1 and V5 electrodes in place, the clinician is still able to access the area of the chest closest to the patient's heart. For example, the clinician is able to use imaging probes in the area of the chest closest to the patient's heart. Third, the clinician may not even be able to attach the V2, V3, and V4 electrodes, because the patient may have wounds or bandages from surgical procedures involving the heart in the area of the chest where the V2, V3, and V4 electrodes are normally positioned. Fourth, electrode V1 is placed near the sternum, but not directly on the sternum, avoiding sternotomy wounds and bandages.

[0038] A less preferred embodiment for the electrode placement of the invention is illustrated in FIG. 5. FIG. 5 also illustrates the electrode placement for six electrodes used to acquire electrical signals from the patient's heart. Again, only two electrodes are attached to the patient's chest. V2 is attached to the patient in approximately the fourth intercostal space at the left border of the patient's sternum. V5 is attached to the patient in approximately the fifth intercostal space at the patient's anterior axillary line. Again, four electrodes are attached to the patient's limbs. The electrodes attached to the right arm, left arm, and left leg acquire electrical signals, while the electrode attached to the right leg generally acts as an electrical ground.

[0039] As illustrated in FIG. 5, electrodes V1, V3, V4, and V6 are not attached to the patient. Thus, leads V1, V3, V4, and V6 corresponding to the omitted electrodes must be derived mathematically. Again, only these four leads need to be derived mathematically. Eight of the leads, namely leads I, II, III, aVR, aVL, aVF, V2, and V5, are generated in the same manner as in a standard ten-electrode, twelve-lead ECG. One disadvantage of the less preferred embodiment is that the mathematically derived V1 lead is not as accurate as the V1 lead generated from the use of the V1 electrode. Since the V1 lead is considered important to clinicians, the embodiment using the V2 and V5 electrodes is less desirable, even though the embodiment produces generally acceptable results.

[0040] In both preferred embodiments, the four missing leads are generated using a mathematical method called multiple-linear regression. Multiple-linear regression is a technique used to compute a prediction of a given data set from associated members of other data sets. In the present invention, these "other" data sets are either ECGs from a hospital's general population, from a sub-population of the hospital's general population, or from ECGs previously acquired from the patient. Preferably, the sub-populations of the hospital's general population are based on one or several parameters, such as sex, race, age, weight, height, or body habitus. Body habitus refers to a combination of body build, height, and weight. In general, the four missing leads are calculated based on the relationship between the available leads and a data set of previously acquired ECGs.

[0041] Preferably, an algorithm uses the multiple-linear regression technique to generate the four missing leads. The input into the algorithm is a data set of previously acquired ECGs. Preferably, the data set consists of previously acquired ECGs from a hospital's general population or from a sub-population of the hospital's general population. Most preferably, the data set consists of previously acquired ECGs from the particular patient.

[0042] Preferably, the data set consists of previously acquired ECGs that have been sampled at a rate of between 120 and 1000 times per second. Thus, the data set consists of twelve columns, corresponding to each of the twelve leads, with hundreds of thousands of rows of samples, corresponding to the voltage values for each of the twelve leads. The algorithm performs multiple-linear regression between the columns of lead data. Specifically, the algorithm performs multiple-linear regression between the columns of lead data corresponding to the electrodes that will be attached to the patient and between the columns of lead data corresponding to an electrode that will not be attached to the patient. The algorithm creates an equation from the previously-acquired ECG data defining the leads that will be missing, due to the omitted electrodes, as a function of the leads that will be available.

[0043] For example, in the most preferred embodiment, the algorithm creates a first equation to determine the value of lead V2 based on the values of leads V1, V5, I, and

II. The inputs to the algorithm are five columns of data corresponding to the previously-acquired ECG voltage values for leads V1, V2, V5, I, and II. The columns of data corresponding to leads V1, V5, I, and II are compared to the column of data corresponding to lead V2. The algorithm generates an equation relating the data in the V1, V5, I, and II lead columns to the data in the V2 lead column by minimizing the sum squared error between the five columns of data. The generated equation is in the following form:

$$y = \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_3 + \beta_4 x_4 \quad [1]$$

where the β_1 , β_2 , β_3 , and β_4 are the expansion coefficients for the equation. An example of an expansion-coefficient equation for lead V2 is as follows:

$$V2 = 1.58 * V1 + 0.23 * V5 - 0.09 * II + 0.89 * I \quad [2]$$

where $y = V2$, $\beta_1 = 1.58$, $x_1 = V1$, $\beta_2 = 0.23$, $x_2 = V5$, $\beta_3 = 0.09$, $x_3 = II$, $\beta_4 = 0.89$, and $x_4 = I$.

[0044] In the same manner, an expansion-coefficient equation is derived for each of the leads corresponding to the omitted electrodes. In the most preferred embodiment, a separate equation is derived for each of leads V2, V3, V4, and V6. Thus, the columns of data corresponding to leads V1, V5, I, and II are compared to the column of data corresponding to lead V3 to generate an expansion-coefficient equation for lead V3. Similarly, the columns of data corresponding to leads V1, V5, I, and II are compared to the column of data corresponding to lead V4 to generate an expansion-coefficient equation for lead V4. Finally, the columns of data corresponding to leads V1, V5, I, and II are compared to the column of data corresponding to lead V6 to generate an expansion-coefficient equation for lead V6.

[0045] In the most preferred embodiment, once the expansion-coefficient equations are derived, the patient's ECG is acquired with only chest electrodes V1 and V5 and the four limb electrodes. From these six electrodes, eight leads are generated in the same manner as for a standard ECG. Four of the twelve leads, however, must be determined using the expansion-coefficient equations previously derived.

Accordingly, the expansion-coefficient equations are used to derive the voltage values for the four missing leads for each individual sample. For example, the expansion-coefficient equation for lead V2 is used to derive the voltage value of lead V2 for each individual sample. In the most preferred embodiment, the voltage values for each sample of leads V3, V4, and V6 are derived in the same manner. With the addition of the data for the four derived leads, the data set comprises a complete twelve-lead ECG.

[0046] FIG. 1 illustrates the apparatus 10 embodying the invention. In the preferred embodiment, the apparatus 10 is a patient monitoring or patient data acquisition device. While any device for acquiring ECG signals (such as, for example, a bedside monitor, transport monitor, or Holter monitor) is contemplated by the invention, the apparatus of the preferred embodiment employs a telemetry-based monitoring device. The apparatus 10 includes six electrodes 12 attachable to a patient 14, leadwires 16 coupled to the electrodes 12, a telemetry unit 18 coupled to the electrodes 12 by leadwires 16, a signal processor 20 wirelessly coupled to the telemetry unit 18, a telemetry monitor 22 coupled to the signal processor 20, and an ECG storage facility 24 coupled to the signal processor 20.

[0047] Before the telemetry system embodied in the apparatus 10 of FIG. 1 is described, it should be understood that the invention could also be implemented in a bed-side monitor. For the bed-side monitor, the electrodes 12 would be coupled directly to the signal processor 20 by leadwires 16 in a conventional manner. Conversely, FIG. 1 illustrates the apparatus 10 including a telemetry unit 18 wirelessly coupled to the signal processor 20 and telemetry monitor 22. Conventional methods of wireless transmission are used to transmit the electrical signals from the telemetry unit 18 to the receiver 28 in the signal processor 20.

[0048] Biopotential signals are often processed by telemetry, a technique that provides a wireless link between the patient and the signal processing components. Thus, clinicians can monitor a patient while the patient has full mobility. Traditional methods of telemetry utilize from three to five electrodes, but are unable to acquire a twelve-lead ECG from these three to five electrodes. The limiting factor in telemetry

is the bandwidth of the signal being transmitted to the signal processing components. Accordingly, traditional telemetry monitors are unable to support the bandwidth necessary to transmit the electrical signals representing an entire twelve-lead ECG.

[0049] In the preferred embodiments of the present invention, four, rather than eight or more, channels of ECG data are transmitted from the telemetry unit 18 to the signal processor 20. As a result, the bandwidth necessary to transmit the electrical signals representing the patient's ECG is reduced by at least half. Due to the reduced number of electrodes and the reduced bandwidth, the telemetry unit 18 is capable of monitoring the electrical activity of the patient's heart while the patient has full mobility. Moreover, the apparatus 10 is capable of acquiring more data from each particular patient or data from more than one patient.

[0050] Referring to FIGS. 1 and 4, according to the method of the most preferred embodiment of the invention, six electrodes 12 are attached to the patient. A first electrode (V1) is attached in approximately the fourth intercostal space at the right border of the patient's sternum. A second electrode (V5) is attached in approximately the fifth intercostal space at the patient's anterior axillary line. Four additional electrodes (LA, RA, LL, and G) are attached to the patient's limbs. Electrical signals are acquired from the six electrodes 12 and transmitted via leadwires 16 to the telemetry unit 18. The electrical signals are amplified and transmitted to the receiver 28 of the signal processor 20.

[0051] In both preferred embodiments, reducing the number of electrodes 12 attached to the patient reduces the number of leadwires 16 and amplifiers (not shown) within the telemetry unit 18 necessary to acquire the electrical signals. Preferably, only six leadwires 16 and four amplifiers within the telemetry unit 18 are necessary for the preferred embodiments of the invention.

[0052] A software module 26 within signal processor 20 uses an algorithm to calculate the expansion-coefficient equations for the four missing leads. The input to the algorithm is, most preferably, a data set of the patient's previously acquired ECGs.

The data set is preferably stored in a hospital ECG storage facility 24 and accessed by the signal processor 20 of the ECG machine 10.

[0053] The apparatus 10 then acquires an ECG for the patient. The telemetry unit 18 transmits the electrical signals from the electrodes 12 to a receiver 28 within the signal processor 20. The four missing leads are calculated by the software module 26 within signal processor 20 using the previously-derived expansion-coefficient equations. All twelve leads, including the four generated leads, are then displayed for the clinician on telemetry monitor 22.

[0054] Various features and advantages of the invention are set forth in the following claims.